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510(k) Summary

DEC - 8 2010

3M

Sponsor Information:

3M Health Care
3M Center, Bldg. 275-5W-06
St. Paul, MN 55144-1000

Contact Person:	Suzanne Leung Regulatory Affairs
Phone Number:	(651) 575-8052
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Date of Summary: November 30, 2010

Device Name and Classification:

Common or Usual Name:	Sterilization Biological Indicator
Proprietary Name:	3M™ Attest™ 1296V Rapid Readout Steam Process Challenge Device 3M™ Attest™ 41382V Rapid Readout Steam-Plus Process Challenge Device
Classification Name:	Indicator, Biological Sterilization Process (21 CFR § 880.2800(a))
Performance Standards:	N/A

Predicate Devices:

- 3M™ Attest™ Steam-Plus Test Pack (formerly ATI Disposable Biological-Plus Test Pack)
- 3M™ Attest™ Rapid Readout 1292 Biological Indicator

Description of Device:

The 3M™ Attest™ 1296V Rapid Readout Steam and 41382V Rapid Readout Steam-Plus Process Challenge Devices (PCDs) are specifically designed to be used in healthcare facilities to routinely challenge 270°F (132°C) dynamic-air-removal (prevacuum) steam sterilization cycles with exposure time of 4 minutes. The changes from the predicate device include an optimization of the PCD for prevacuum steam cycles and a replacement of the biological indicator (BI) from one based on a visual color change growth readout to one based on a fluorescence readout.

The PCD consists of multiple layers of medical index cards, some of which are die-cut to contain monitoring products. The pack is overwrapped and secured with a label. A sheet of moisture absorbent material (absorbent pad) is placed over the wrapped PCD pack, and then the PCD pack is placed in a vented film pouch as the fully-assembled PCD sold to the customer. This construction regulates air removal and steam penetration and presents a challenge to better monitor multiple pulse vacuum-assisted steam cycles.

Each Attest 1296V Rapid Readout Steam PCD is supplied with a 1292 Rapid Readout biological indicator, which contain bacterial endospores of *Geobacillus stearothermophilus*. The Attest 41382V Rapid Readout Steam-Plus PCD is supplied with a 1292 Rapid Readout biological indicator and one SteriGage chemical integrator.

Each PCD has a chemical process indicator on the outside of the PCD that changes from yellow to dark brown/black when exposed to steam. In addition, there is a chemical process indicator on the Attest BI that changes color from rose to brown when exposed to steam. The Attest Rapid Readout biological indicator is specifically designed for a rapid fluorescent readout when used in conjunction with the 3M™ Attest™ Auto-reader. A fluorescence change indicates a steam sterilization process failure. Attest Rapid Readout biological indicator controls are provided with the PCD.

Indications for Use:

Use the Attest 1296V Rapid Readout Steam and 41382V Rapid Readout Steam-Plus Process Challenge Devices to monitor 132°C (270°F) dynamic-air-removal (prevacuum) steam sterilization cycles with exposure time of 4 minutes.

Comparative Data for Determining Substantial Equivalence of New Device to Predicate Device:

Multiple lots of 3M™ Attest™ Rapid Readout Steam and Rapid Readout Steam-Plus Process Challenge Devices were evaluated following applicable FDA guidance and standards.

- FDA's *Guidance for Industry and FDA Staff, Biological Indicator (BI) Premarket Notification [510(k)] Submissions;* October 4, 2007
- ANSI/AAMI ST79: 2006, A1:2008, A2:2009 *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*

A Summary of the nonclinical testing is shown.

Test	Acceptance Criteria	Result
Resistance Performance: • 1296V Rapid Readout Steam PCD vs. AAMI Towel Pack in a 4 minute, 132°C (270°F) cycle	• 1296V PCD has resistance greater than or equal to the AAMI Towel Pack • All PCDs are killed in a 4 minute, 132°C (270°F) cycle	Pass
Resistance Performance: • 41382V Rapid Readout Steam-Plus PCD vs. AAMI Towel Pack in a 4 minute, 132°C (270°F) cycle	• 41382V PCD has resistance greater than or equal to the AAMI Towel Pack • All PCDs are killed in a 4 minute, 132°C (270°F) cycle	Pass
Resistance Performance: • 1296V Rapid Readout Steam PCD vs. predicate 41380 Steam-Plus Test Pack in a 4 minute, 132°C (270°F) cycle	• 1296V PCD has resistance greater than or equal to the predicate 41380 Steam-Plus Test Pack • All PCDs are killed in a 4 minutes, 132°C (270°F) cycle	Pass
Resistance Performance: • 41382V Rapid Readout Steam-Plus PCD vs. predicate 41380 Steam-Plus Test Pack in a 4 minute, 132°C (270°F) cycle	• 41382V PCD has resistance greater than or equal to the predicate 41380 Steam-Plus Test Pack • All PCDs are killed in a 4 minutes, 132°C (270°F) cycle	Pass

The results of these evaluations showed that the new 3M™ Attest™ 1296V Rapid Readout Steam and 41382V Rapid Readout Steam-Plus Process Challenge Devices are substantially equivalent to the predicate device, the 3M™ Attest™ 41380 Steam-Plus Test Pack (formerly ATI Disposable Biological-Plus Test Pack) cleared under K925496, in terms of its intended use, physical properties and technological characteristics. There are no new questions of safety or effectiveness.

The disposable 3M™ Attest™ Rapid Readout Steam and Rapid Readout Steam-Plus Process Challenge Devices present a challenge to the sterilization process equivalent to the biological indicator AAMI towel pack recommended by ANSI/AAMI ST79: 2006,

A1:2008, A2:2009. The biological indicator contained within complies with ANSI/AAMI/ISO 11138-1:2006/(R)2010 and ANSI/AAMI/ISO 11138-3:2006/(R)2010. The chemical integrator complies with the performance requirements of the FDA for chemical integrators as well as the international voluntary standard ANSI/AAMI/ISO 11140-1:2005.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Dr. Suzanne Leung
Regulatory Affairs
3M Company
3M Center, Building 275-5W-06
St. Paul, Minnesota 55133-3275

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Re: K101910
Trade/Device Name: 3M Attest 1296V Rapid Readout Steam Process Challenge Device 3M Attest 41382V Rapid Readout Steam-Plus Process Challenge Device
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: JOJ, FRC
Dated: December 1, 2010
Received: December 2, 2010

Dear Dr. Leung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

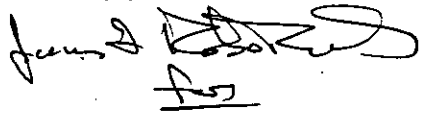
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

DEC - 8 2010

510(k) Number (if known): K101910

Device Name: 3M™ Attest™ 1296V Rapid Readout Steam Process Challenge Device
3M™ Attest™ 41382V Rapid Readout Steam-Plus Process Challenge Device

Indications For Use:

Use the Attest 1296V Rapid Readout Steam and 41382V Rapid Readout Steam-Plus Process Challenge Devices to monitor 132°C (270°F) dynamic-air-removal (prevacuum) steam sterilization cycles with exposure time of 4 minutes.

Prescription Use _____ AND/OR Over-The-Counter Use ___X____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
'vision of Anesthesiology, General Hospital
ection Control, Dental Devices

10(k) Number: K101910